UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,862	12/24/2003	Melton B. Affrime	025444.1056-US02	9343

26853 7590 09/11/2006

COVINGTON & BURLING, LLP
ATTN: PATENT DOCKETING
1201 PENNSYLVANIA AVENUE, N.W.
WASHINGTON, DC 20004-2401

EXAMINER	
KIM, VICKIE Y	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/743,862	AFFRIME ET AL.	
	Examiner	Art Unit	
	Vickie Kim	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/24/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of application

Claims 1-51 are presented for examination

Information Disclosure Statement(IDS)

The information disclosure statement (IDS) is submitted on 12/24/03. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. Please refer to applicants' copy of the 1449 submitted herewith.

Claim Rejections - 35 USC § 112, 1st

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Scope of Enablement

1. Claims 1-51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims because the specification, while being enabling for treating allergic or inflammatory conditions, **does not reasonably provide enablement for** preventing said conditions using a single drug as claimed.

Attention is directed to In re Wands, 8 USPQ 1400 (CAFC 1988) at 1404 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a

disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls) at 547 the court recited eight factors:

1) *The nature of the invention:*

The instant invention is drawn to a method of treating but also preventing allergic or inflammatory conditions such as rhinitis, asthma, urticaria, dermatitis.

2) *The state of the prior art:*

As the state of art recognizes, there are various path-etiologic factors(e.g.bio-pathways and pathogens) involved in inflammatory or allergic reactions which has not been completely understood.

The state of the art recognizes that the significance of particular drug treatment for modifying different aspects of biological activity cannot be predicted a priori and furthermore, the state of the art also recognizes that no single drug treatment is effective for all the pathogens and etiologies causing inflammation or allergic reactions.

Generally, art acknowledges that the conditions associated with cardiovascular diseases can be reduced or treated but not completed prevented or inhibited because all the possible causes are unknown or completely avoidable. There are no known compound which have been demonstrated to prevent or cure completely a disease.

It isnoted that the claims must be given their broadest interpretation. Therefore, the interpretation of claims (i.e. prevention of

inflammation or allergic reactions as claimed) should be made based on the full definition of the term "prevention" including "forestall a disease completely" wherein the claims become not enabled.

Since this assertion is contrary to what is known in medicine, proof must be provide that this revolutionary assertion has merits. The existence of such a "silver bullet" is contrary to our present understanding of pharmacology.

3) *The relative skill of those in the art:*

The relative skill of the those in the art is high.

4) *The predictability of the art:*

The high degree of unpredictability in the treatment of inflammation or allergic conditions is well known in the art. A slight change in the structure of the drug would drastically change its influence on receptor binding activity. Many times, therapeutic activities or toxic effects are corresponding to dose and selectivity(receptor binding), etc. Furthermore, the level of patient's immune system would play critical role in progress.

Furthermore, a treatment using a pharmaceutical composition containing multiple active ingredients or carriers having different chemical structures and modes of actions, their interaction, co-action, e.g. synergism etc. is even more unpredictable.

5) *The breadth of the claims:*

Applicant's assertion that the inventive compounds, its composition would be useful for prevention of all the possible upcoming attack or event does not commensurate with the scope of the objective enablement, especially in view of the high degree of unpredictability and the limited working examples.

6) *The amount of guidance/working examples:*

The specification fails to provide substantial evidence to prove the claimed allegation. Furthermore, applicant states that claimed subject matter is achieved by inhibiting histamine production. First of all, there is no 100% inhibition shown. And histamine is only biological material that causes inflammation or allergic reaction. Therefore, there is no substantial teaching or guidance for prevention that can be achievable by DCL administration.

The specification provides lack of evidential support substantially where any skilled artisan can not clearly understand how the claimed invention is achieved at the time of the invention with the information provided and thus, the claims are considered not enabled with the information given.

7) *Quantitation of undue experimentation.*

Since insufficient teaching and guidance have been provided in the specification, one of ordinary skill in the art, even with high degree of skill,

would not be able to use the compound for prevention of inflammatory or alleric conditions as claimed without undue experimentation.

The true fact of the state of the art in said therapy is expressed well, "The significance of particular drug treatment for modifying different aspects of biological activity cannot be predicted a priori but must be determined from the case to case by painstaking experimental study and when the above factors are weighed together, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study " to determine the efficacy.

Claim Rejections - 35 USC § 112,2nd

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claim 14 is a relative term which renders the claim indefinite. The term "substantially the same" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear what level of the closeness constitutes of "substantially". Therefore, one would not know what the metes and bounds of the claims are.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Alberg et al(US5595997), or alternatively in view of Claritin® instruction sheet.

The claims are drawn to a method of treating or preventing allergic and inflammatory conditions of the skin or airway passages such as allergic rhinitis, atopic dermatitis, urticaria or allergic asthma, using an effective amount of desloratadine while avoiding a food effect.

Alberg(US'997) teaches a method of treating allergic reactions such as allergic rhinitis, allergic asthma, urticaria, dermatitis using a therapeutically effective amount of desloratadine(DCL), see col. 7-8. Alberg also teahes that DCL treats allergic conditions without the concomitant liability of adverse side-effects associated with other non-sedating antihistamines such as appetite stimulation, weight gain, gastrointestinal distress or nausea, see abstract.

Firstly, prevention of allergic and inflammatory conditions are inherently possessed by the teaching of Alberg's patent because the patent teaches treatment of allergic condition, in other words, unwanted conditions are free via treatment, and thus the claims inherently met and prevention of allergic condition are achieved in same patient group with same dosage regimen. Thus, the claimed subject matter is naturally

achieved when the allergic reaction is free and treated. And thus, The patented teaching embraces prophylaxis as well as treatment,, see col. 1, lines 67.

Secondly, All the critical elements required by the instant claims are well taught in the cited reference and thus, the claimed subject matter is not patentably distinct over the prior art of the record. For instance, US'997 teaches the therapeutically effective amount the treatment present in about 0.1 to 10mg per day, preferably 0.1 to 5mg, see col. 8, lines 30-42. US'997 also teaches a dosage formulation and regimen such as tablet, aqueous or non-aqueous liquid, emulsions, (at col.9, lines 52-67). Food effects is inherent feature, because US'997 did not explicitly mentioned about food effect, one would have been envisioned that there is no particular food effect and the patient in US'997 administer the medication with or without and expected to have substantially same therapeutic effectiveness(bioavailability), absent evidence to the contrary. The claimed limitation recited in preamble would not render the claims patentable because the claimed invention relates a treatment of the allergic condition but not directed to pharmacokinetic enhancement.

Or alternatively, the pharmacokinetic and the food effects can be titrated or determined by routine optimization(see PTO-892, Nomier's teaching-1996). Additionally, one would have been readily envisioned absence of food effects because Alberg's emphasis was made on advantages of adverse effect free activity which were associated with conventional non-sedating antihistamine which requires drug administration without food(see instruction sheet available in OTC drug such as Loratadine(claritin®),for instance, instruction teaches "take Claritin® on empty

stomach". Thus,one would have been easily envisioned that absence of food effect is one of advantages taught by Alberg's teaching.

All the claimed invention has been well taught and the claims are met by the cited reference.

All the limitations required by the instant claims are well taught and thus properly included in this rejection.

Conclusion

1. No claim is allowed.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

VICKIE KIM
PRIMARY EXAMINER

Vickie Kim
September 5, 2006
Art unit 1618